510(k) Summary

Submission

Submitted by:

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Application Prepared:

Alaron Technologies, LLC

(contact for additional

Jamal Rushdy

information)

990 Park Center Drive, Suite H

Vista, CA 92083

(760) 599-1674 Phone, (760) 599-1675 Fax

Date of preparation:

December 15, 2000

Device

Common Name:

Anchor

Trade Name:

dj Orthopedics Tibial Anchor

Classification Name:

Single/multiple component bone fixation appliances and accessories

Predicate Device:

Innovasive Devices Intratunnel Tibial Fixation Fastener, K983560

Description and Intended Use

The dj Orthopedics Tibial Anchor is a ribbed anchor type device to facilitate soft tissue fixation such as a tendon or ligament within the tibial bone. The dj Orthopedics Tibial Anchor is a two-part device consisting of outer spreader part and an inner screw to facilitate fixation of the graft to the tibial tunnel and to the anchor.

The dj Orthopedics Tibial Anchor is intended for use in bone fixation of soft tissue grafts during cruciate ligament reconstruction surgeries. This is the same indication as the predicate device.

Technological Characteristics

The implant is designed to be inserted into the tibial tunnel. The two ends of the tendon graft are passed over the outside of the spreader arms and then pass into the spreader through side windows, exiting out of the tunnel through side holes in the spreader collar. The tibial screw is then inserted into the center spreader hole. The screw is rotated into the spreader that moves the spreader arms outward, compressing the tendon graft and securing the construct.

The predicate device is an anchor device designed to facilitate soft tissue fixation. The dj Orthopedics and Innovasive predicate devices are both designed for insertion into a prepared tibial tunnel, utilizing a pin which expands a sleeve, compressing the graft against the tunnel creating fixation.

Pullout testing of the dj Orthopedics Tibial Anchor shows that the performance characteristics are substantially equivalent to previously published performance characteristics of similar fixation methods.

Conclusion

The predicate device and the dj Orthopedics Tibial Anchor are both anchor type devices used to facilitate soft tissue fixation such as a tendon or ligament within the tibial bone. Both devices utilize a two-part pin and sleeve construct design to compress the graft to the tibial tunnel. The dj Orthopedics Tibial Anchor is offered in sizes that are comparable to the size range of the predicate device. The intended uses are the same.



MAR 21 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

DJ Orthopedics, LLC Mr. Jamal D. Rushdy c/o Alaron Technologies, LLC 990 Park Center Drive, Suite H Vista, California 92083-8339

Re: K003960

Trade Name: DJ Orthopedics Tibial Anchor

Regulatory Class: II

Product Code: MBI and HWC Dated: December 15, 2000 Received: December 21, 2000

Dear Mr. Vernon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: dj Orthopedics, LLC

510(k) Number (if known): K O 3960

Device Name: dj Orthopedics Tibial Anchor

Indications For Use:

The dj Orthopedics Tibial Anchor is intended for use in the fixation of soft tissue grafts in cruciate ligament reconstruction surgeries.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109) (Optional Format 1-2-96) (Division Sign-Off)

Division of General, Restorative

and Neurological Devices

510(k) Number_

K003960